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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,967	03/28/2000	Bruno Guy	50019/006001	7903

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CLARK & ELBING LLP  
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BOSTON, MA 02110

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/02/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/403,967**

Applicant(s)  
**Guy et al**

Examiner  
**Portner**

Art Unit  
**1645**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 7, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 29-58 is/are pending in the application.
- 4a) Of the above, claim(s) 29-38, 40-42, 45, and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39, 43, 44, and 46-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 29-58 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1645

### **DETAILED ACTION**

Claims 29-58 are pending.

Claims 39 and 46 have been amended.

Claims 29-38,40-42, 45 and 58 are withdrawn.

Claims 39, 43-44, 46-57 are under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION**

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 7, 2003 has been entered.

### ***Rejections/Objections Withdrawn***

3. The Abstract was entered at page 52.

4. Claims 39, 50-51 and 57, in light of the amendment of claim 39 to no longer read on a liposome composition that comprises a plasmid therefore no longer recites a genus of invention that is obvious over claims 1,9-11,26 of U.S. Patent No. 6,126,938.

5. Claims 39 and 43 rejected under 35 U.S.C. 103(a) as being unpatentable over Guy et al, as applied to claims 39, 44, 49-57 above, in view of Epand et al ( US Pat. 5,283,185), in light of new grounds of rejection over Cover et al below.

Art Unit: 1645

6. Claims 39 and 43 rejected under 35 U.S.C. 103(a) as being unpatentable over Guy et al, as applied to claims 39, 44, 49-57 above, in view of Lockhoff et al ( US Pat. 4,855,283)in light of new grounds of rejection over Cover et al below.

***Rejections Maintained***

7. Claims 39, 44, 49-57 rejected under 35 U.S.C. 102(e) as being anticipated by Guy et al (US Pat. 6,126,938, different inventive entity), in light of the claims still permitting the “salts thereof” to be in liposome form and Guy et al disclose a lipid mixture that is a combination of cationic lipid salts (see col. 11, lines 54-57) and urease in combination with the cationic lipid salt is disclosed (see col. 12, lines 1-4), for reasons of record in paper number 16.

***Response to Arguments***

8. The rejection of claims 39, 44, 49-57 under 35 U.S.C. 102(e) as being anticipated by Guy et al (US Pat. 6,126,938, different inventive entity), is traversed on the grounds that the “lipids used in the method of this claim are not in the form of liposomes”.

9. It is the position of the examiner that while the lipids of claim 39 must not be in the form of liposomes, the claims still permit the “salts thereof (see rejection under 35 U.S.C. 112, second paragraph below)” to be in liposome form and Guy et al disclose a lipid mixture that is a combination of cationic lipid salts (see col. 11, lines 54-57). Guy et al still anticipates the instantly claimed invention.

<u>Instant Application</u>	<u>Guy et al ‘ 938</u>
Method of inducing an immune response	Method of inducing an immune response
TH-1	TH-1 (IgG2a, see figures 2B, 3A, 4A)
H.pylori is antigenic protein	Antigenic protein, Urease,adhesin,vacA (see 7, lines 30- 34,col. 8, lines 17-27)
cationic lipid salt liposomes (new claim 39)	MPLA (see col. 12, line 34;col. 6, lines 29-42; DC-Chol (cationic lipid salt (col. 11, lines 54-57),

Art Unit: 1645

Administering  
(defined to include a single or multiple steps)

Administering  
(defined to be multiple steps (see claims))  
see page 18, lines 1-9 and page 23, lines 20-38 and page 24, lines 1-8)

In the instantly claimed invention, liposomes are permitted when the compound is a cationic lipid salt, rather than just a cationic lipid (newly amended claim 39).

***New Grounds of Objection/Rejection***

***Claim Objections***

10. Claims 39, 43-44, 46-57 are objected to because of the following informalities: All of the elected claims recite non-elected invention and are therefore objected to for minor informalities as not being directed to the examined invention. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

11. Claims 39, 43-44, 46-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39, 43-44, 46-57 recite non-elected invention and therefore do not distinctly claim Applicant's elected invention.

Art Unit: 1645

Claim 39 recites the phrase “said lipid is not provided in the form of a liposome”. It is not clear whether the quoted phrase is intended to include “or a salt thereof”; does the claim include liposomes made from cationic lipid salts? This rejection could be obviated by amending the claim to recite “said lipid. --or a salt thereof-- “ is not provided in the form of a liposome”.

Claim 49 defines the immunogenic agent to be agent of newly amended claim 39; how is claim 49 further limiting of claim 39 from which it depends? Claim 39 and 49 recite the same combination of claim limitations.

Claim 50 should depend from claim 39 and not claim 49 as claim 49 is not further limiting of newly amended claim 39.

***Claim Rejections - 35 U.S.C. § 102***

12. Claims 39, 43,46-48, 49, 51-54, 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Cover et al (US Pat. 6,054,132; effective filing date February 26, 1992).

Cover et al disclose the instantly claimed method of inducing an immune response against *Helicobacter pylori* (see Cover et al, claims 4-6), wherein the *H.pylori* antigen is a protein referred to as vacuolating toxin, the method comprising the step of:

administering the *Helicobacter pylori* purified protein antigen together with an adjuvant and a pharmaceutically acceptable carrier to an animal (mammal, see col. 15, line 53 and col. 16, line 28), or a human (see claims 4-6), which include patients (see col. 1, lines 10-16) wherein the adjuvant is defined to be cationic lipids (see col. 16, Example 6, line 49) and the route is either by

Art Unit: 1645

the enteral or parenteral route (see Cover et al, claims 5 and 6). The parenteral route would by definition include subcutaneous, intramuscular and intradermal routes of administration.

Inherently the reference anticipates the instantly claimed invention because by all comparable data, the invention of Cover et al is the same or equivalent invention now claimed. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

### ***Conclusion***

13. This is a non-final action.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Michetti et al (US Pat. 6,290,962; filing date February 23, 1994).disclose a method of inducing an immune response, wherein the method comprises the step of administering a Helicobacter polypeptide (whole urease (see col. 17, line 19), the alpha subunit (see claims) or the beta subunit (see claims)) or a Helicobacter peptide (see col. 10, line 42; col. 16, lines 7-8) in

Art Unit: 1645

purified form (see claims 1, 3,6, col. 35 and claims 21, 23, 26) together with a saponin (see col. 35, claims 8- 9, line 59 "saponins" which would include QS-21; and claim 29, line 50).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 22, 2003

  
**LYNETTE R. F. SMITH**  
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